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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,751	08/30/2001	Dan Stoianovici	56436(71699)	8459

21874 7590 08/15/2003

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EXAMINER

NGUYEN, VI X

ART UNIT PAPER NUMBER

3731

DATE MAILED: 08/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No:

09/943,751

Applicant(s)

STOIANOVICI ET AL. *en*

Examiner

Victor X Nguyen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 18-25, 29-36, 39, 42, 43, 46 and 47 is/are rejected.
- 7) ☒ Claim(s) 16, 17, 26-28, 37, 38, 40, 41, 44 and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 April 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the following reference sign (s) (#170, #175, #188 are not shown in figures 1-7) as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 13-15, 18-25, 29-34, 36, 39, 42 and 46-47 are rejected under 35 U.S.C. 102

(b) as being anticipated by Paltieli (U.S. 5,647,373).

Paltieli shows in figures 1, 4 and 5-6 a device having all the limitation of claims 1 and 46-47, including: a first arm (42) arranged to support the penetrating member (6). A first drive mechanism (25) couples to the first arm (42); and wherein the penetrating member (6) proximal portion disposes in the target area.

Regarding claims 2 and 3, wherein the first arm (42) rotates to support the penetrating member (6). A second drive mechanism (45) couples to the penetrating member to cause the penetrating member to rotate about a long axis; and wherein the first (25) and second (45) drive

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mechanisms are configured so that rotating of the penetrating member is independently controlled.

Regarding claims 4 and 5-6, wherein the first (25) and second (45) drive mechanisms are configured so as to rotate of the penetrating member with different rotational speeds.

Regarding claims 7 and 8-9, wherein the second arm (43) couples to the first drive mechanism (25). The second arm (43) further includes a guide mechanism (fig. 2) which has the penetrating member (6); and wherein the guide mechanism is capable of guiding differently sized the penetrating member (6).

Regarding claims 13 and 14-15, wherein the first drive mechanism (25) includes a screw (23) coupled to the first arm (42); and wherein the first drive mechanism (25) includes a motor (45) coupled to the screw; wherein the first arm (42) translates in one of the direction responsive to the direction of rotation of the motor.

Regarding claims 18 and 39, wherein a controller (32) arranges to select and control the first and second drive mechanisms.

Regarding claims 19-20, wherein the controller (32) includes a plurality of pre-established penetrating member (6) from an initial position to the target area.

Regarding claims 21-22, wherein the controller (32) rotates of the penetrating member (6) and also to arrange to rotate the penetrating member with different rotational speeds.

Regarding claims 23 and 24-25, wherein the controller (32) translates the penetrating member in a back and forth manner; the device further includes a sensor (labeled in col. 2, lines 64-67 and col. 3, lines 1-5); and wherein the penetrating member is capable of performing any one of injecting therapeutic agents into the target area (col. 3, lines 8-41).

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Regarding claims 29 and 42, wherein a first arm (42) arranges to support the penetrating member (6). A first drive mechanism (25) couples to the first arm (42); and wherein the penetrating member (6) proximal portion disposes in the target area. A second arm (43) couples to the first drive mechanism (25). A second drive mechanism (45) couples to the penetrating member (6) to cause the penetrating member to rotate about a long axis.

Regarding claims 30-31, wherein the first (25) and second (45) drive mechanisms are configured so as to rotate of the penetrating member with independently controlled.

Regarding claims 32 and 33-34, the first (25) and second (45) drive mechanisms are configured so as to rotate of the penetrating member with different rotational speeds; and wherein the second arm (43) includes a guide mechanism (fig. 5) which includes the penetrating member (6).

Regarding claim 36, wherein a screw (23) couples to the first arm (42); a motor (45) couples to the screw (23); and wherein the first arm (42) translates in one the direction responsive to the direction of rotation of the motor.

Claims 1-6 and 46-47 are rejected under 35 U.S.C. 102 (b) as being anticipated by Stoianovici et al (WO 98/36688).

Stoianovici et al show in figures 1-3, a device having all the limitation of claims 1 and 46-47, including: a first arm (39) arranges to support the penetrating member (7). A first drive mechanism (37) couples to the first arm (39); and wherein the penetrating member (7) proximal portion disposes in the target area.

Regarding claims 2 and 3, wherein the first arm (39) rotates to support the penetrating member (7). A second drive mechanism (fig. 1) couples to the penetrating member to cause the

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penetrating member to rotate about a long axis; and wherein the first and second drive mechanisms are configured so that rotating of the penetrating member is independently controlled.

Regarding claims 4 and 5-6, wherein the first and second drive mechanisms are configured so as to rotate of the penetrating member (7) with different rotational speeds.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 10-12, 35 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paltieli (U.S. 5,647,373).

Regarding claims 10-12, 35 and 43, Paltieli fails to disclose the first arm and the second arm includes a detachable portion and a latching mechanism. It would have been obvious to one having ordinary skill in the art at the same time the invention was made to construct the Paltieli' device with the first arm and the second arm includes a detachable portion and a latching mechanism, since it has been held to be within the general skill of worker in the art to allow the operator to replace the needle conveniently and to prevent the needle being contaminated as a matter of obvious engineering choice. In re Larson, 144 USPQ 347 (CCPA 1965); In re Lockart, 90 USPQ 214 (CCPA 1951).

Allowable Subject Matter

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5. Claims 16-17, 26-28, 37-38, 40-41 and 44-45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose wherein the first drive mechanism includes a linear guide which to restrain motion of the first arm and a sliding member which is secured to the first arm.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 6,400,979 to Stoianovici

U.S. Pat. No. 5,660,185 to Shmulewitz

U.S. Pat. No. 6,337,994 to Stoianovici

U.S. Pat. No. 6,251,121 to Saadat

U.S. Pat. No. 6,086,544 to Hibner

U.S. Pat. No. 6,080,181 to Jensen

U.S. Pat. No. 5,766,126 to Anderson

U.S. Pat. No. 6,106,511 to Jensen


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Victor X Nguyen
Examiner
Art Unit 3731

vn ✓
August 4, 2003


MICHAEL J. MILANO
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